Sim, Hughes, Ashton & McKay LLP
Barristers & Solicitors

Sim & McBurney
Patent & Trade Mark Agents

6th Floor, 330 University Avenue
Toronto, Ontario, Canada M5G 1R7

Tel. (416) 595-1155 • Fax (416) 595-1163

DATE: March 29, 2004

Your Ref: - **Our Ref: 9577-25 LAB**

TO:Commissioner for Patents United States Patent & Trademark Office	FAX #703 872 9306	PHONE #

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FROM: Dr. Lola A. Bartoszewicz, Ph.D. / (416) 595 1155 ext. 200

COMMENTS: RE : U.S. 09/845,497

ODIDI ET AL

TITLE :EXTENDED RELEASE PHARMACEUTICALS

FURTHER TO THE AMENDMENT AND RESPONSE DATED MARCH 8, 2004, ATTACHED IS THE DECLARATION EXECUTED BY THE CO-INVENTORS.

CERTIFICATE OF TRANSMISSION BY FACSIMILE (37 CFR 1.8) Applicant(s): Isa Odidi and Amina Odidi			Docket No. 9577-25 LAB
Serial No. 09/845,497	Filing Date May 1, 2001	Examiner Alton Pryor	Group Art Unit 1616

Invention:
EXTENDED RELEASE PHARMACEUTICALS

I hereby certify that this DECLARATION EXECUTED BY CO-INVENTORS
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PATENT

Attorney Docket 9577-25

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CERTIFICATE OF MAILING

I hereby certify that this paper is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Box Fee Amendment; Commissioner for Patents, Washington, DC 20231 – Sent via facsimile
March 8, 2004 by Cheryl Alphonso

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Applicant:	Isa Odidi and Amina Odidi	:	Paper No.:10
Serial No.	09/845,497	:	Group Art Unit: 1616
Filed:	May 1, 2001	:	Examiner: Alton N. Pryor
For:	Extended Release Pharmaceuticals		

DECLARATION UNDER 37 C.F.R. 1.132

Box Fee Amendment
Commissioner for Patents
Washington, DC 20231

Isa Odidi and Amina Odidi declare that:

1. They are co-inventors of and are familiar with the present U.S. Patent Application Serial No. 09/845,497, and they are familiar with the Official Actions issued in the present application and the reference cited by the Examiner; U.S. Patent No. 6,099,859 to Cheng et al.

2. The extended release pharmaceutical active formulation of the present invention has an encasement coat comprising a polymeric film. The encasement coat is soluble in a pH of above 5.0 and comprises polymer and PEG. As such, the polymer must be a dissolvable one in a pH of above 5.0 and may be selected from enteric cellulose esters, polyvinyl acetate phthalate, methacrylic acid copolymers and any mixtures thereof.

3. U.S. Patent No. 6,099,859 to Cheng *et al.* is directed to a controlled release pharmaceutical formulation containing a core portion. The core is coated with a semi-permeable membrane that is permeable to the passage of biological fluids but impermeable to the passage of the drug in the core. As such, the <u>membrane itself is not pH reactive and does</u>

not dissolve. This is due to the fact that Cheng teaches the use of non-enteric cellulose esters that are semi-permeable. In the present application, it is clearly stated that the encasement coat is not semi-permeable.

4. Due to the different amounts and types of polymers used in the present invention compared to that of Cheng, the release profile of the drug within the formulations is different as is shown in the attached Table 1:

5. The amount of polymer used in the formulation of the present invention was less that 50% (ie. 45.0%) and the polymer used was soluble in a pH of above about 5.0 as claimed. The amount of polymer used in the membrane coating of the Cheng formulation was 85% and the type was a non-soluble cellulose acetate.

6. These results show that the release rates of the drug depends on the amount and the type of cellulose polymer used. Lowering the amount of polymer used by Cheng would not substantially affect the shape of the curve. Therefore, since these tests show that cellulosic polymers listed in U.S. Patent No. 6,099,859 *et al.* are not equivalent to the present invention.

7. Isa Odidi and Amina Odidi further declare that all statements made herein of his/her own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,

March 9, 2004

Isa Odidi

March 9, 2004

Amina Odidi

TABLE 1

Formulaes of Intellipharmaceutics and Cheng's products

Please note that the model drug chosen to make the comparison was the same drug used in the example in Cheng's patent. This drug is Metformin hydrochloride.

1. Intellipharmaceutics formulation (US 09845497)

Metformin coated tablet

Content in Core	%
Metformin Hcl	64.46
Microcrystalline Cellulose	32.46
Polyvinyl pyrolidone USP	2.58
Magnesium stearate	0.50
Total	100

Content of Coat	%
Methacrylic acid copolymer type A	40.50
Methacrylic acid copolymer type B	4.50
Talc	36.00
Red Iron Oxide	5.00
Titanium Dioxide	2.75
Polyethylene glycol 600	11.25
Total	100

2. Cheng's formulation (US Patent 6,099,859)

Metformin coated tablet

Content in Core	%
Metformin Hcl	90.54
Polyvinyl pyrolidone (USP)	4.38
Sodium tribasic phosphate	4.58
Magnesium stearate	0.50
Total	100

Content of Coat	%
Cellulose acetate (398-10)	85.00
Triacetin	5.00
Polyethylene glycol 400	10.00
Total	100

Figure1. Dissolution Profile of Model Drug Showing a significant difference between Odidi et al and Chang et al membrane teachings: Dissolution condition: Apparatus 2, 75 RPM, pH 7.5